

of the practice of the process with a materially different product, the Office Action provided that the present process claims could be practiced using "Italian salad dressing." Applicant agrees that "Italian salad dressing" is a materially different product. However, Applicant respectfully submits that no evidence has been presented showing that at least two different long chain polyunsaturated fatty acid-containing microbial oils can be obtained from Italian salad dressing. Moreover, no evidence supporting the addition of Italian salad dressing to infant formula has been presented. Additionally, no evidence that Italian salad dressing contains omega-3 or omega-6 fatty acids has been provided.

Accordingly, it is respectfully submitted that the restriction requirement has been improperly applied. As can be seen from the comprehensive search already conducted by the Examiner, art pertaining both to the product claims and to the process claims would be uncovered in a single search. Additionally, Applicant notes that no obviousness type double patenting rejection could issue should the restriction requirement be maintained and Applicant elect to file a divisional application. However, Applicant affirms the election as set forth in the Office Action, should the restriction requirement not be withdrawn.

As a brief summary of the present invention, Applicant has discovered that oil-producing microbes can be induced to produce desirable oils containing long chain polyunsaturated fatty acids (PUFAs). Such PUFAs are useful for various purposes. Oils from various microbes can be blended with each other, or with other PUFA-containing oils to provide useful compositions. The utility of these compositions is not predicated upon various ratios of the oils with each other. It is predicated upon the fact that microbial oils containing long-chain PUFAs are used in the compositions.

Turning now to the rejections, each will be addressed in turn. The specification was objected to and claims 29, 30, 33,

34, 36-41, 43-46, 49, 52-56, 58-66 were rejected under 35 U.S.C. § 112 first paragraph as "failing to provide sufficient exemplary matter to support claims as broad as claim 29 wherein the amounts or ratios between the components are not recited." Applicant respectfully traverses this rejection and requests its withdrawal.

The objection to the specification appears to be that it does not contain a written description. Such an objection is clearly incorrect. For example, at page 5, line 5, the specification provides that the oils (plural) specifically disclosed and utilized in the specification each contain a single desirable PUFA. Throughout the specification, reference is had to a plurality of microbial oils. At page 7, line 34, the specification provides that long chain PUFA-containing microbial oils from at least two microorganisms can be obtained and blended together to provide a desired composition. Thus, the invention claimed in claim 29, for example, is specifically described in the specification. Similarly, language conforming to that used in each claim is found in the specification. Accordingly, a sufficient written description is present in the specification to support each claim.

Where a specification as originally filed describes the invention in substantially the same terms as those employed in the claims, the description requirement of the statute (35 U.S.C. § 112) has been complied with. Ex parte Hradcovsky et al., 214 USPQ 554 (PTOBA 1982). Here, the terms employed in the claims are substantially the same terms as those used in Applicant's specification to describe the invention. Accordingly, the description requirement of the statute has been complied with and both the objection and the rejection under the first paragraph, 35 U.S.C. § 112 should be withdrawn.

In explaining the rejection under the first paragraph, the Office Action contains the statement that the claims fail to recite any amounts or ratios of the components of the composition. Applicant notes that this language also was used in

the Office Action as grounds for a rejection under 35 U.S.C. § 112, second paragraph. Specifically, claims 29, 30, 33, 34, 36-41, 43-46, 49, 52-56 and 58-66 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because they fail to recite any amounts or ratios for the components of the claimed compositions. Applicant respectfully traverses both these rejections and requests their withdrawal. Those of skill in the art would have no trouble understanding the metes and bounds of the present invention as claimed. For example, claim 29 is to a composition which comprises a blend of at least two long-chain polyunsaturated fatty acid-containing microbial oils. Thus, any composition comprising a blend of at least two long-chain polyunsaturated fatty acid-containing microbial oils would be encompassed by the language of this claim. The language is plain and the meaning unmistakable. The metes and bounds are precisely set forth. See Shatterproof Glass Corp. v. Libbey Owens Ford Co., et al., 225 USPQ 634 (Fed. Cir. 1985). In that case, a party had argued that certain claims of a patent were indefinite and thus invalid because they did not recite the size of certain elements or the quantity or quality of other elements in the claim (i.e., amounts). The Federal Circuit did not accept this argument, stating that the amount of detail required to be included in the claims depended on the particular invention and the prior art and was not to be viewed in the abstract but in conjunction with whether the specification was in compliance with the first paragraph of § 112. According to the Federal Circuit, all the claims need to do is, when read in light of the specification, reasonably apprise those skilled in the art, both of the utilization and scope of the invention. That has been done in the present case.

Applicant respectfully submits that this rejection appears to be a rejection for undue breadth. Such a rejection would be improper. In re Marzocchi et al., 169 USPQ 367 (CCPA 1971). A broad claim which employs well-known language conventionally used in the art to which the invention pertains, and which is of the

same scope as the description of the invention as stated in the disclosure, is not objectionable under the second paragraph of 35 U.S.C. § 112, since it is neither "too broad" in the sense of embracing a concept not stated in the original disclosure, nor is it vague or indefinite. In re Kamal et al., 158 USPQ 320 (CCPA 1968); In re Borkowski et al., 164 USPQ 642 (CCPA 1970). A rejection of undue breadth must be based on a discrepancy between the scope of the disclosure and the scope of the claims. In re Steinhauser et al., 162 USPQ 595 (CCPA 1969). As explained above, the language of the present claims tracks the language of the specification.

It would be unfair and improper to limit Applicant to only claims to Applicant's preferred embodiments, i.e. those claims setting forth ratios. The present claims employ well-known language conventionally used in the art to which the invention pertains and find ample support from the description of the invention as stated in the disclosure. Thus, they are not indefinite.

Applicant has defined his invention as compositions including microbial oils which contain long-chain PUFAs. Applicant respectfully submits that the invention, as defined by Applicant, is particularly pointed out and distinctly claimed. It may be that the Examiner has studied Applicant's disclosure, formulated a conclusion as to what the Examiner regards is the broadest invention supported by the disclosure, and then determined that the claims are broader than the Examiner's conception of what the invention is. If such has occurred, it is error. In re Borkowski, 154 USPQ 642, 645 (CCPA 1970).

For all the foregoing reasons, it is respectfully submitted that the claims should not be rejected for not including ratios or quantities. Such would be an error of law. The claims particularly point out what Applicant regards as his invention. The language used in the claims is clear. Those of skill in the art would have no difficulty in determining whether they were

encroaching upon the scope of the claims. Accordingly, each rejection under 35 U.S.C. § 112 should be withdrawn.

Additionally, claims 29-35, 43, 45-51, and 58-64 were rejected under 35 U.S.C. § 103 as being unpatentable over Ensor et al. This rejection is respectfully traversed. Ensor et al. were said to disclose feed compositions comprising various oils such as marine, animal, plant and vegetable oils containing fatty acids such as arachidonic acid, eicosapentaenoic acid and docosahexaenoic acid. The claimed subject matter was said to differ from the disclosure of Ensor et al. in claiming specific ratios of fatty acids and specific oil sources. (Applicant respectfully suggests that this rejection for claiming specific ratios appears inconsistent with the earlier § 112 rejection for the failure to claim specific ratios.) The determination of the optimum amounts and/or proportions of ingredients to employ was said to be well within the skill of the art. The choice of specific oils was deemed to be a matter of obvious alternative.

Ensor et al. do not teach or suggest the present invention. Ensor et al. relate to methods of feeding ruminants and to feed compositions and methods of preparing the same for use in the feeding methods. Ensor teaches that fatty acids including ARA and DHA when fed to ruminants will stimulate growth and fattening of the ruminants. There is absolutely no disclosure by Ensor et al. that microbial oils are a suitable source of long-chain polyunsaturated fatty acids. Indeed, Ensor et al. teach the opposite. They teach that marine, animal and plant or vegetable oils are sources of the fatty acids. By marine oils, Ensor et al. are referring to fish oils, as can be seen by reference to column 2, lines 42-44. In contrast, the present invention pertains to blends utilizing long-chain polyunsaturated fatty acid-containing microbial oils. Additionally, Ensor et al. do not recognize the need for supplementation of human nutrition by polyunsaturated fatty acids, particularly infants, vegetarian, and pregnant or nursing women. That fish and other oils were known to contain polyunsaturated fatty acids is not disputed by

Applicant. However, Applicant's discovery that microbial oils containing long chain polyunsaturated fatty acids could be utilized in various compositions, including those able to satisfy deficiencies in human diets, is not taught or suggested by Ensor et al. As all of Applicant's claims require such microbial oils, it is respectfully requested that this rejection be withdrawn.

Moreover, with respect to this rejection, the Office Action contains no evidence upon which the choice of specific oils was "deemed" to be a matter of obvious alternative. Certainly, Ensor et al. do not provide such a suggestion if one type of "specific oil" is considered to be microbial oil. Should evidence particularly within the scope of the Examiner's knowledge provide the basis for such a statement, the Examiner is requested pursuant to 37 CFR § 1.107 to set forth the basis for this statement in an affidavit so that Applicant has a fair opportunity to contravene it.

For all the foregoing reasons, it is respectfully suggested that this rejection has been overcome and should be withdrawn.

Claims 29, 36-44, 54-62, 65 and 66 were rejected under 35 U.S.C. § 103 as being unpatentable over Cotter et al. Cotter et al. were said to disclose nutritional compositions comprising marine oils and gamma linolenic acid. The marine oils were said to include eicosapentaenoic acid and docosahexaenoic acid. Again, the present claims were rejected because they were said to differ from the primary reference only in claiming specific ratios and specific oils.

Cotter et al. nowhere teach or suggest the use of microbial oils. All of the present claims require microbial oils. Cotter et al. obtained their oils from marine sources. As is known to those of skill in the art, marine oils are fish oils. Cotter et al. relate to a method of treatment for individuals suffering from cardiovascular disease. The method comprises providing a composition which is a mixture of a carbohydrate source, a protein source, and at least one lipid selected from the group consisting of gamma linolenic acid, eicosapentaenoic acid,

docosahexaenoic acid, sterodonic acid and linolenic acid to a patient. There is no disclosure or suggestion of any composition containing fatty acid-containing microbial oils. There is no teaching or suggestion of the use of microbial oils in supplements for infants or pregnant or nursing women. The claimed subject matter of the present application is completely different from that taught by Cotter et al.

This rejection also contains an assertion that the selection of a specific oil is deemed to be a matter of obvious choice. Again, Cotter et al. do not teach or suggest anything about microbial oils. If microbial oil is a type of oil "deemed" to be an obvious choice, the Examiner is requested to set forth the basis of that assertion in an affidavit as required under 37 CFR § 1.107, so that Applicant may respond to the facts underlying such assertion.

For all the foregoing reasons, Applicant respectfully submits that this rejection has been overcome and its withdrawal is solicited.

Applicant appreciates the citation of additional references to show the state of the art. Applicant notes that no rejection has been based upon these references.

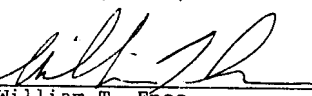
#### CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the application now is in condition for allowance as reasons for the withdrawal of each rejection have been presented. Accordingly, prompt passage of this application to issue and allowance of the present claims is earnestly solicited.

Respectfully submitted,

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